

REMARKS

Claims 37-44 and 50-69 have been examined. Claim 55, 65 and 68 have been amended. Claims 63, 64 and 67 have been canceled. Reconsideration of the claims, as amended, is respectfully requested.

Claim Rejections - 35 USC 101

Claims 63 and 64 have been rejected under 35 USC 101 as being inoperative. Claims 63 and 64 have been canceled, thereby rendering this rejection moot.

Claim Rejections - 35 USC 112

Claims 55-64 have been rejected under 35 USC 112, second paragraph, as being indefinite. Claim 55 has been amended to claim "the receiving member", thereby overcoming this rejection as to claims 55-62. Claims 63 and 64 have been canceled thereby rendering this rejection moot as to these claims.

Claim Rejections - 35 USC 102

Claims 55-56 and 61-64 have been rejected under 35 USC 102(b) as being anticipated by Bepak. This rejection is respectfully traversed in part and overcome in part.

As now amended, independent claim 55 claims an aerosolization device for delivering a liquid medicament to a patient's respiratory system. The aerosolization device comprises a receiving member configured to receive an ampoule containing a liquid medicament, and an aerosol generator that is in fluid communication with the receiving member. The aerosol generator is configured to receive at least some of the liquid medicament from the receiving member and to aerosolize the liquid medicament. The aerosol generator comprises an aperture plate having a plurality of apertures, and a vibratable element that is mechanically linked to the aperture plate such that vibration of the vibratable element causes the aperture plate to vibrate, thereby ejecting droplets of the liquid medicament. Further, the aerosolization device includes

means for creating first and second openings in the ampoule to permit the liquid in the ampoule to drain into the aerosol generator.

In this way, the aerosolization device may produce both a drain vent and a drain opening. Such a configuration is particularly useful when draining liquids from ampoules with relatively large volumes.

In contrast to the aerosolization device of claim 55, the Bepak reference describes an atomizer that is far different. More specifically, the Bepak reference describes various atomizers that do not utilize ampoules where both a drain opening and a vent opening are created to permit liquid from the ampoule to drain into an aerosol generator. For example, the embodiment of Fig. 6 of Bepak illustrates a liquid supply means 71 that consists of gelatin capsules 72 that are formed on a disposable strip 75. When an actuator 74 is depressed, "the capsules are ruptured." Page 11, line 6. As defined in "The American Webster Dictionary", rupture means: "The process of breaking open or bursting." Hence, actuator 74 does not pierce the gel caps, but applies sufficient pressure to cause the gel caps to rupture. This is illustrated in Fig. 6 which shows that actuator 74 does not pierce the capsule, but simply provides a mechanical force that causes the capsule to rupture in a single location.

The rupturing process is far different than creating two openings in an ampoule to permit the liquid to drain out. Instead, with Bepak, the capsule is pressured to cause the capsule to burst. Such a process is ill suited for dispensing relatively large volumes of liquid as with the present invention. Hence, claim 55 which has been amended to claim means for forming first and second openings in the ampoule is distinguishable and in condition for allowance. Claims 56, 61 and 62 depend from claim 55 and are distinguishable for at least the reasons recited in connection with claim 55.

Claim Rejections - 35 USC 103

Claims 37-44 and 50-54 are rejected under 35 USC 103(a) as being unpatentable over Bepak in view of Ivri. This rejection is respectfully traversed.

As pending, claim 37 claims a method for providing a liquid medicament to an aerosolization device for delivery to a patient's respiratory system. Among other steps, claim 37 includes the steps of "creating a first opening in an ampoule, the ampoule containing the liquid medicament; exposing the first opening in the ampoule to the liquid feed system; and creating a second opening in the ampoule to permit the liquid from the ampoule to drain into the liquid receiving region of the feed system."

As described above, the Bepak reference fails to teach or suggest the creating of two openings in an ampoule to permit the liquid from the ampoule to drain into the liquid receiving region. Rather, with the embodiment of Fig. 6 of Bepak, a gel capsule is pressurized until it bursts and ejects the liquid out of the capsule. Such a process is far different from creating two openings to permit the liquid to drain out of the capsule. Hence, claims 37-44 and 50-54 are distinguishable without amendment, and it is respectfully requested that the section 103 of these claims in view of Bepak and Ivri be withdrawn.

With regards to the rejection of claim 65, this claim includes, among other limitations, an ampoule containing a liquid medicament and having a first opening that is in fluid communication with the receiving member, and a second opening that permits the liquid medicament to flow through the first opening and into the receiving member. As previously described, the Bepak patent fails to teach such a limitation by describing a rupturable gelatin capsule. Hence, claim 65 which has been amended to include such limitations is distinguishable.

Claims 66-69 have been rejected under 35 USC 103(a) as being unpatentable over Bepak and Ivri in view of Singier. Claims 66-69 depend from claim 65 which is distinguishable over Bepak and Ivri as previously described. The Singier patent also fails to teach such limitations. More specifically, the Singier patent describes a bottle that is used with intravenous injections and includes a self sealing device that permits access to the liquid by perforation (such as by using a needle to pierce the self sealing device). Hence, the Singier patent also fails to teach or suggest an ampoule with first and second openings to permit the liquid to flow through the first opening and to the receiving member. Moreover, there is no teaching or suggestion to combine an IV bottle with an aerosolization device that uses an ampoule. Still further, the

Appl. No. 09/812,987

PATENT

Amdt. dated January 8, 2004

Reply to Office Action of November 19, 2003

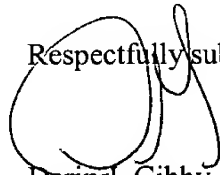
Bespak aerosolizer uses a rupturable gel cap and would be inoperable with an IV bag. Hence, claims 66-69 are distinguishable for at least these additional reasons.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



Darin J. Gibby
Reg. No. 38,464

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: (303) 571-4000
Fax: (303) 571-4321
DJG/cl
60113691 v1